

UNITED STATES PATENT AND TRADEMARK OFFICE

Examiner:	Laura C. Hill	Art Unit:	3761
Re:	Application of:	Arnold R. Leiboff	
	Serial No.:	10/672,053	
	Confirmation No.:	7183	
	Filing Date:	September 26, 2003	
	Title:	Intestinal Insertion Tube with Sewing Ring	
	Customer Number:	22846	

APPEAL BRIEF UNDER 37 C.F.R. §41.37

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

September 4, 2007

Dear Sir:

On June 4, 2007, appellant, through his attorney, appealed from the final rejections of claims 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 86-95 set forth in an Office Action dated February 5, 2007 for this application. An Appeal Brief was filed August 6, 2007.

A Notification of Non-Compliant Appeal Brief was mailed August 31, 2007 indicating that the Appeal Brief filed August 6, 2007 did not contain a concise explanation of the subject matter defined in each of the independent claims.

This Amended Appeal Brief is therefore being submitted by appellant in support of the patentability of claims 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 86-95 of this application. For the reasons set forth below, it is believed that the rejections in the Office Action dated February 5, 2007 should be reversed.

A. REAL PARTY IN INTEREST

The real party in interest of the above-identified application is the inventor, Dr. Arnold R. Leiboff.

B. RELATED APPEALS AND INTERFERENCES

At this time, there are no related appeals or interferences.

C. STATUS OF CLAIMS

Claims 1-17, 40-42, 44, 66-68, 78 and 80-95 are pending in this application, claims 18-39, 43, 45-65, 69-77 and 79 having been canceled. Claims 2-4, 9, 80 and 82-84 have been withdrawn from consideration. Claims 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 85-95 have therefore been examined and all have been rejected. Appellant has therefore appealed the final rejections of claims 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 85-95.

Claim 78 is the only independent claim, the remaining claims, i.e., claims 1, 5-8, 10-17, 40-42, 44, 66-68, 78, 81 and 85-95, depending directly or indirectly on claim 78. The text of the claims on appeal is found in the Claims Appendix.

D. STATUS OF AMENDMENTS

An Amendment Under 37 C.F.R. §1.116 was filed on May 7, 2007. In an Advisory Action mailed May 22, 2007, the Examiner indicated that the Amendment would be entered for the purposes of Appeal.

E. SUMMARY OF CLAIMED SUBJECT MATTER

The present invention as defined in independent claim 78, the only independent claim, relates to a tube (10) for attaching to bowel (90) which comprises a tubular body (12) having a front end adapted to be inserted into the bowel (90) (see the specification at, for example, page 6, lines 12-16), and a sewing ring (44a) arranged in connection with the tubular body (12) and including an undercut rear surface defining a circumferentially extending notch (see Fig. 6 and the specification at, for example, page 8, line 28 to page

9, line 5 and page 11, line 27 to page 12, line 2). The sewing ring (44a) has a portion which projects rearward and outward away from the tubular body (12) such that the notch is defined partly by the rearwardly and outwardly extending portion and such that a rearward edge of the sewing ring (44a) extends rearward of a forward end of the notch (see the specification at, for example, page 9, lines 2-4). The bowel (90) is attachable to the sewing ring (44a) by passing a filament through the bowel (90) and the sewing ring (44a) (see the specification at, for example, page 9, lines 18-28).

Although reference is made to certain drawings and portions of the specification above for the purpose of explaining the claimed invention and the features thereof to comply with requirements under 37 C.F.R. §41.37, the scope of the claims is not being limited to any of the illustrated embodiments and appellants reserve the right to interpret the claims to cover other structure whether disclosed elsewhere in the specification of the instant application, in the specification of applications incorporated by reference therein or otherwise, to the extent permissible.

F. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. The first ground of rejection to be reviewed on this appeal is whether Bartholomew et al. (U.S. Pat. No. 4,650,473), applied in a rejection of claims 78, 1, 5-8, 10, 12-17, 40-42, 44, 66-68, 81 and 85-95 under 35 U.S.C. §102(b) and in a rejection of claim 11 under 35 U.S.C. §103, discloses all of the features of the embodiments of the invention set forth in claims 78, 10-12, 17, 66, 68, 81, 86-90 and 95.

2. The second ground of rejection to be reviewed on this appeal is whether Bartholomew et al. discloses all of the features of the embodiment of the invention set forth in claim 1 and thus anticipates this embodiment under 35 U.S.C. §102(b).

3. The third ground of rejection to be reviewed on this appeal is whether Bartholomew et al. discloses all of the features of the embodiments of the invention set forth in claims 5-8 and 67 and thus

anticipates these embodiments under 35 U.S.C. §102(b).

4. The fourth ground of rejection to be reviewed on this appeal is whether Bartholomew et al. discloses all of the features of the embodiments of the invention set forth in claims 13-16, 40-42 and 44 and thus anticipates these embodiments under 35 U.S.C. §102(b).

5. The fifth ground of rejection to be reviewed on this appeal is whether Bartholomew et al. discloses all of the features of the embodiment of the invention set forth in claim 85 and thus anticipates this embodiment under 35 U.S.C. §102(b).

6. The sixth ground of rejection to be reviewed on this appeal is whether Bartholomew et al. discloses all of the features of the embodiments of the invention set forth in claims 91-93 and thus anticipates these embodiments under 35 U.S.C. §102(b).

7. The seventh ground of rejection to be reviewed on this appeal is whether Bartholomew et al. discloses all of the features of the embodiment of the invention set forth in claim 94 and thus anticipates this embodiment under 35 U.S.C. §102(b).

G. ARGUMENT

First Ground of Rejection

Bartholomew et al. does not disclose, teach or suggest features of independent claim 78, upon which claims 10-12, 17, 66, 68, 80, 81, 86-89 and 95 depend directly or indirectly.

Specifically, Bartholomew et al. does not disclose, teach or suggest a sewing ring having the following features:

1. “a portion which projects rearward and outward from” a tubular body in connection with which the sewing ring is arranged, with a circumferentially extending notch being defined partly by this rearwardly and outwardly extending portion;

2. a rearward edge which “extends rearward of a forward end of [the] notch”; and
3. a form or design which enables bowel to be attachable thereto by passing a filament through the bowel and the sewing ring.

As to the first feature, in the claimed invention, there is a (single) portion of the sewing ring which projects both rearward (in a direction toward the rear of) and outward (in a direction away from) the body. In Bartholomew et al., ridge 17b projects outward from the body 10 as it appears to be oriented perpendicular to axis A but does not project from the body 10 in a direction toward the rear of the body 10. Although ridge 17b has a rear face or edge which faces the rear of the body 10, there is no projecting of this face or edge from the body in a direction toward the rear of the body. Thus, ridge 17b projects only outward and not rearward from the body.

As to the second feature, in view of the perpendicular extension of the ridge 17b relative to the axis A, it is not possible that the ridge 17b has a rearward edge (an edge at the rear) which extends rearward of a forward edge of the saddle 17 between the ridges 17a and 17b. Rather, the forward edge of the saddle 17 is at the same position relative to the axis A as the rearward edge of the ridge 17b, i.e., they are one and the same surface. This is required in view of the flatness of the rear surface of the ridge 17b and its relative orientation, perpendicular, to the axis A.

The Examiner states in the Advisory Action dated May 22, 2007 that Bartholomew has a rearward distally disposed edge which extends rearward/behind forward proximally disposed end of the notch formed by the ridge 17b. However, this construction of Bartholomew is untenable because the rearward distally disposed edge of ridge 17b does not partly define the notch, but rather it is the forward proximally disposed edge of the ridge 17b which partly defines a notch and this forward proximally disposed edge of the ridge 17b does not extend rearward of the forward end of the notch.

As to the third feature, the ridge 17b, as well as ridge 17a, should not be considered comparable to

a “sewing” ring as set forth in claim 78 because the ridges 17a, 17b do not function in the same way to achieve the same purpose as the sewing ring in the present claimed invention. Ridges 17a, 17b are provided to retain filaments and no mention is made of forming either of these ridges from a material which enables filament to be passed therethrough. By contrast, the sewing ring in the present claimed invention is used in a sewing step whereby filament is passed through the sewing ring and bowel and enables the bowel to be attached to the sewing ring, and thus to the tube the sewing ring is arranged in connection with. To this end, the sewing ring may be made from a soft, penetratable material as set forth in the specification. The absence of any disclosure in Bartholomew et al. of constructing the ridges 17a, 17b to enable filament to be passed therethrough, or otherwise passing a filament through the ridges 17a, 17b, should preclude consideration of the ridges 17a, 17b as a sewing ring as set forth in claim 78.

In view of the fact that the ridge 17b of Bartholomew et al. does not have at least three features of the sewing ring as set forth in claim 78, Bartholomew et al. cannot anticipate or render obvious the embodiment of the invention set forth in claim 78 or the embodiments set forth in claims 10-12, 17, 66, 68, 81, 86-89 and 95 which depend directly or indirectly therefrom.

Second Ground of Rejection

Bartholomew et al. does not disclose a sewing ring which is substantially circular and angled rearward, and having a tip which extends rearward of an inward end of the notch as set forth in claim 1.

Ridge 17b is undeniably not circular, when interpreted to mean having the form of a circle, a plane curve everywhere equidistant from a given fixed point, the center. The Examiner stated in the Advisory Action that a “circular” ridge may include a circular, non-linear curve such as the ridge 17b of Bartholomew et al. In this regard, a request is hereby made for the Examiner’s meaning of the term “circular”.

Regardless of the Examiner’s meaning, the Examiner’s position is respectfully traversed on the

grounds that the ridge 17b is simply not in the form of a circle, and also not non-linear. Rather, ridge 17b extends in a common plane over only a discrete segment of a circle. It cannot extend over a circle because it is prevented from extending over the entire circumference, and thus being circular, in view of the presence of the wing 16.

Moreover, the tip of the ridge 17b (the uppermost point) does not extend rearward of the inward end of the notch but rather is actually forward of the rear face or edge of the ridge 17b which partly defines the notch. Therefore, the tip of ridge 17b does not extend rearward of the inward end of the notch but rather exactly the opposite, it is forward of the inward end of the notch.

Since Bartholomew et al. does not disclose, teach or suggest a tube for attaching to bowel including all of the features of claim 1, it cannot anticipate the embodiment of the invention set forth in this claim.

Third Ground of Rejection

Bartholomew et al. does not disclose a sewing ring which comprises a sheath having a portion extendable to cover an area of attachment of the bowel to the tubular body as set forth in claim 5, upon which claims 6-8 and 67 depend directly or indirectly.

The Examiner stated in the Advisory Action that since the term “sheath” has not been set forth with reasonable clarity, deliberateness and precision, the term has been given its plain meaning and thus nib 19 constitutes a sheath.

Initially, a request is hereby made for the Examiner’s meaning of the term “sheath”, i.e., the “plain meaning” of this term.

As used in the specification, a sheath, element designated 36, is extended from the tube over the area of attachment of the tube to the bowel and is then attached to the bowel to enclose this area (as shown in Figs. 3-5).

The Examiner's position that nib 19 is a sheath is respectfully traversed on the grounds that the nib 19 has absolutely no similarity in function to the sheath in the invention. Nib 19 is not extendable in any manner.

Moreover, there is no ridge which extends outward from the outer surface of the body and retains such a sheath as set forth in claim 6, or any portion which is rolled as set forth in claim 67.

Since Bartholomew et al. does not disclose, teach or suggest a tube for attaching to bowel including all of the features of claims 5-8 and 67, it cannot anticipate the embodiments of the invention set forth in these claims.

Fourth Ground of Rejection

Bartholomew et al. does not disclose a tubular body which comprises at least one circumferential triangular lip arranged at an end of a tubular portion as set forth in claim 13, upon which claims 14-16, 40-42 and 44 depend directly or indirectly.

As shown in Fig. 6, the body 10 includes "circumferential" triangular lips 42, lips 42 which extend around the circumference of the body.

In the Office Action dated February 5, 2007, the Examiner pointed to wings 16 of Bartholomew et al. to correspond to the circumferential triangular lips in the claimed embodiments. Wings 16 extend laterally from the base or patient contacting portion of the body (see col. 3, lines 60-61). Wings 16 do not extend circumferentially at an end of a tubular portion.

Moreover, wings 16 do not include a forward angled proximal surface (claims 14 and 41) and a distal surface perpendicular to an outer circumferential surface of the body (claims 15 and 42). Wings 16 are also not arranged rearward of the sewing ring (claim 16), but rather are arranged forward of the ridge 17b, considering the notch between ridges 17a and 17b to be rearward of ridge 17b.

Since Bartholomew et al. does not disclose, teach or suggest a tube for attaching to bowel including all of the features of claims 13-16, 40-42 and 44, it cannot anticipate the embodiments of the invention set forth in these claims.

Fifth Ground of Rejection

Bartholomew et al. does not disclose a tube for attaching to bowel which includes a tubular body and a sewing ring arranged around the circumference of the tubular body as set forth in claim 85.

In this embodiment, the sewing ring 44a is arranged around the circumference of the tubular body 12, i.e., extends around or encircles the tubular body 12.

Ridge 17b of Bartholomew et al. does not extend around or encircle the body 10 but rather extends on only one side of the body 10. On one side of the body 10, there is a wing 16 and on the side opposite the wing 16, the ridge 17b is formed (col. 4, lines 17-19). Thus, ridge 17b clearly does not extend around the circumference of the body 10, and moreover cannot extend around the circumference of the body as it would interfere with the wing 16.

Since Bartholomew et al. does not disclose, teach or suggest a tube for attaching to bowel including all of the features of claim 85, it cannot anticipate the embodiment of the invention set forth in this claim.

Sixth Ground of Rejection

Bartholomew et al. does not disclose a tube for attaching to bowel which includes an attachment device including a sewing ring and a tie seat for supporting a tie used to tie the bowel around the body, and a rolled bowel sheath which is part of or separate from the unitary attachment device as in the embodiments set forth in claims 91-93.

The Examiner's position that nib 19 is a rolled bowel sheath is respectfully traversed on the grounds

that the nib 19 has absolutely no similarity in function to the rolled bowel sheath in the invention. Nib 19 is not rolled in any manner.

Moreover, there is no ridge which extends outward from the outer surface of the body and retains such a sheath as set forth in claim 92.

Since Bartholomew et al. does not disclose, teach or suggest a tube for attaching to bowel including all of the features of claims 91-93, it cannot anticipate the embodiments of the invention set forth in these claims.

Seventh Ground of Rejection

Bartholomew et al. does not disclose a tube for attaching to bowel which includes a sewing ring which is made of a soft, elastic, pliable plastic and is separate from the tubular body as set forth in claim 94.

Initially, there is no disclosure in Bartholomew et al. of making the ridge 17b, or ridge 17a, from a soft, elastic, pliable plastic. The purpose of this in the invention is to enable a filament to be passed through the sewing ring when attaching a tube, to which the sewing ring is connected, to bowel. Thereafter, in the Interview Summary dated May 7, 2007, the Examiner stated that the term “separate” was given its broadest possible reasonable interpretation.

A request is hereby made for the Examiner’s interpretation of the term “separate”.

It is the applicant’s position that separate means independent. In this embodiment of the invention, the sewing ring 44a may be part of a unitary attachment device 48a which is an independent body as shown in Figs. 6A and 6B which is placed onto the tubular body 12.

Ridge 17b in Bartholomew et al., which has been considered to correspond to the sewing ring in the present claimed invention, is integral and not independent of the body 11.

Since Bartholomew et al. does not disclose, teach or suggest a tube for attaching to bowel including

all of the features of claim 94, it cannot anticipate the embodiment of the invention set forth in this claim.

H. CONCLUSION

Bartholomew et al. does not disclose several features of the present claimed invention, including a sewing ring with a rearwardly and outwardly projecting portion, a circular sewing ring, a sewing ring which is arranged around the circumference of a tubular body, a bowel sheath which is extended or unrolled to cover an area of attachment of the body to bowel, circumferential triangular lips on the tubular body, and a separate sewing ring.

Therefore, upon reason and authority, it is respectfully requested that the Board reverse the final rejection.

The fee for filing an Appeal Brief, appellant having qualified for small entity status, is submitted herewith.

An early and favorable action on the appeal is earnestly solicited.

FOR THE APPELLANT
Respectfully submitted,

/Brian Roffe/

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CLAIMS APPENDIX

1. The tube of claim 78, wherein said sewing ring is substantially circular and is angled rearward, a tip of said sewing ring extending rearward of an inward end of said notch.
5. The tube of claim 78, further comprising a bowel sheath having a portion extendable to cover an area of attachment of the bowel to said body.
6. The tube of claim 5, wherein said body includes a ridge extending outward from an outer surface, said ridge being arranged to retain said bowel sheath.
7. The tube of claim 6, wherein said ridge is circumferential, extending outward from an outer, circumferential surface of said body.
8. The tube of claim 5, wherein said bowel sheath is made of molded latex or silicone.
10. The tube of claim 78, wherein said body is formed from an injection molding process.
11. The tube of claim 78, wherein said body is transparent.
12. The tube of claim 78, wherein said distal end portion of said body includes at least one thread for mating with a screw cap or seal.
13. The tube of claim 78, wherein said body includes at least one circumferential triangular lip

arranged at said proximal end of said tubular portion.

14. The tube of claim 13, wherein said at least one triangular lip has a proximal surface angled forward to facilitate insertion of said tube into the bowel.

15. The tube of claim 14, wherein said at least one triangular lip further includes a distal surface substantially perpendicular to an outer circumferential surface of said body to prevent the secured bowel from slipping off of said body.

16. The tube of claim 13, wherein said sewing ring is arranged rearward of said at least one triangular lip.

17. The tube of claim 78, wherein said sewing ring is arranged proximate said distal portion of said body.

40. The tube of claim 13, wherein said body has a side arm extending from a side thereof and said at least one triangular lip has planar surfaces.

41. The tube of claim 40, wherein each of said at least one triangular lip has a proximal surface angled forward to facilitate insertion of said tube into the bowel.

42. The tube of claim 41, wherein each of said at least one triangular lip further includes a distal surface substantially perpendicular to an outer circumferential surface of said body to prevent the secured

bowel from slipping off of said body.

44. The tube of claim 40, wherein said at least one triangular lip comprises a plurality of triangular lips.

66. The tube of claim 78, wherein said body includes a side arm extending from a side thereof, said side arm being adapted to mate with an outflow tube at a distal end.

67. The tube of claim 5, wherein said portion of said bowel sheath is rolled and is adapted to be unrolled over and to cover the area of attachment of the bowel to said body.

68. The tube of claim 78, wherein said sewing ring is monolithically formed with said body.

78. A tube for attaching to bowel, comprising:

a tubular body having a front end adapted to be inserted into the bowel; and

a sewing ring arranged in connection with said tubular body, including an undercut rear surface defining a circumferentially extending notch, said sewing ring having a portion which projects rearward and outward away from said body, said notch being defined partly by said rearwardly and outwardly extending portion such that a rearward edge of said sewing ring extends rearward of a forward end of said notch,

whereby the bowel is attachable to said sewing ring by passing a filament through the bowel and said sewing ring.

81. The tube of claim 78, wherein the bowel is attachable to said sewing ring by passing a

filament through the bowel and said sewing ring while the bowel is clamped to said sewing ring.

85. The tube of claim 78, wherein said sewing ring is arranged around the circumference of said body.

86. The tube of claim 78, wherein said body has a proximal end adapted to be inserted into the bowel and a distal end, said projecting portion of said sewing ring projecting toward said distal end.

87. The tube of claim 78, wherein said notch is defined by said sewing ring such that said sewing ring and said notch are fixed relative to one another.

88. The tube of claim 78, wherein said sewing ring is monolithic.

89. The tube of claim 78, further comprising a side arm extending from a side of said body, said body having a proximal end adapted to be inserted into the bowel and a distal end, said side arm being adapted to mate with an outflow tube at a distal end, said sewing ring being arranged proximate said distal portion of said body for securing said body within an open end of the severed bowel.

90. The tube of claim 89, wherein said sewing ring is part of an unitary attachment device for attaching an edge of the bowel to said body, said attachment device further comprising a tie seat for supporting a tie used to tie the bowel around said body.

91. The tube of claim 90, wherein said unitary attachment device further comprises a rolled

bowel sheath adapted to roll over and cover the area of attachment of the bowel to said body.

92. The tube of claim 90, wherein said body includes a ridge extending outward from an outer surface of said body, further comprising a rolled bowel sheath separate from said unitary attachment device, said ridge being arranged to retain said bowel sheath, said unitary attachment device being arranged over an unrolled portion of said bowel sheath to thereby secure said bowel sheath to said body.

93. The tube of claim 92, wherein said ridge is circumferential, extending outward from an outer, circumferential surface of said body.

94. The tube of claim 89, wherein said sewing ring is made of a soft, elastic, pliable plastic and is separate from said body.

95. The tube of claim 89, wherein said sewing ring is monolithic with said body.

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EVIDENCE APPENDIX

Not applicable.

U.S. patent application Ser. No. 10/672,053
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RELATED PROCEEDINGS APPENDIX

Not applicable